## REMARKS

With this response, claims 10-58 are pending. Claims 39, 40, 42, 43, and 47 have been canceled without prejudice or disclaimer of the underlying subject matter. Claims 24, 44, and 49-58 have been amended. Support for the claim amendments can be found throughout the specification and the claims as originally filed. Additional support for such amendments and new claims will be apparent to one of skill in the art. Upon entry of the foregoing amendments, claims 10-38, 41, 44-46 and 48-58 will be pending. Support for the amendments to the specification can be found throughout the application, in particular at page 5, lines 14 to 31; figures 3C, 3D, 4A, 4B, and 6A-6D; and the examples, including examples 4, 5, and 6. These sections describe two subjects with impaired glucose tolerance, referred to as D01 and D02, and two subjects with type 2 diabetes mellitus, referred to as D07 and D09. Each of the subjects had results of saline infusion and GLP-1 infusion. In example 6 and Figures 6A-6D, there is described a comparison of normalized spectral power during saline infusion and GLP-1 infusion for two subjects, D02 and D07. Hence, from this there should be four graphs to compare, saline infusion for D02, GLP-1 infusion for D02, saline infusion for D07, and GLP-1 infusion for D07. The description in the specification refers to the 4 graphs in the figures. For example, on page 23, lines 3-4, of the specification, it states "[t]hese [Figures 6A-6D] correspond to the data shown in Figures 3C and 3D, and Figures 4A and 4B." Accordingly, Applicants submit that the amendments find support in the specification and no new matter is being added by the present amendments.

Initially, Applicants acknowledge and thank the Examiner for indicating that "[t]he objection to the specification and claims and the rejections under 35 U.S.C. 112, second paragraph, 35 U.S.C. 103(a) and 35 U.S.C. 102(b) for composition claims (i.e. canceled claims 1-9) are withdrawn." *Office Action mailed December 27, 2004*, at page 2.

## I. Rejections Under 35 U.S.C. § 102

Claims 39, 40, 42, and 43 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 98/08531. This rejection is respectfully traversed, reconsideration is requested for at least the reasons that follow.

The Examiner alleges that WO 98/08531 "as shown in the abstract, Examples 1 and 2 and claims 1-13, clearly teaches a method of reducing mortality and morbidity after myocardial infraction by administering GLP-1 and a GLP-1 analog or derivative thereof at a dose effective to normalize blood glucose since normalizing blood glucose will reduce the risk of cardiovascular or cerebrovascular events" citing Applicants' own application at page 1, lines 18-21 as support. *Office Action* at page 3.

Applicants maintain that WO 98/08531 fails to disclose all of the limitations of the present claims. However, to facilitate prosecution, claims 39-40 and 42-43 have been canceled without prejudice to or disclaimer of the underlying subject matter. Accordingly, the rejection of claims 39-40 and 42-43 under 35 U.S.C. § 102(b) is moot. Reconsideration and withdrawal of this rejection are respectfully requested.

## II. Rejection under 35 U.S.C. § 112, First Paragraph

Claims 10-38, 41 and 44-54 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." *Office Action* at page 4. Claim 47 has been canceled without prejudice, as such, Applicants respond to the rejection as it applies to claims 10-38, 41, 44-46, and 48-54.

The Examiner alleges that Applicants' claim amendment filed on October 20, 2004 contains "new matter because the original specification does not appear to support who has not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM)." *Id*, page 4. The Examiner contends that "there is no disclosure in the specification" for this language. *Id.* Applicants respectfully disagree for at least the reasons that follow.

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually

invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). The Examiner appears to argue that no possession is shown because the precise claim language is not used in the specification. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972). All that is required is that a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification. *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996). The skilled artisan would recognize that Applicants were in possession of the invention as now claimed at the time of filing.

Applicants maintain that the specification and claims as originally filed adequately support the amended claim language. *See, e.g.*, specification at page 1, lines 15 to page 2, line 3; page 3, lines 3-10; page 4, lines 1-8; and page 6, lines 1-9. As described in the specification, see in particular page 1, line 22 to page 2, line 3, IGT is a distinct condition which may or may not develop into NIDDM. Applicants' instant claims merely clarify that the methods are directed to treating the condition of IGT.

Moreover, the examples in the specification disclose studies that were performed using ten subjects who were "divided into two groups" based on "their plasma glucose response to an oral glucose tolerance test." *See, e.g.*, specification at page 14, lines 7-17. Five of the subjects had IGT and 5 had NIDDM. *Id.* The skilled artisan reading the specification would recognize that the IGT subjects in the examples had not been diagnosed with non-insulin dependent diabetes mellitus (NIDDM), or else they would not have been included in the IGT group but instead placed in the NIDDM group. Accordingly, Applicants submit that they contemplated at the time of filing as one subject population the treatment of subjects with IGT whose inability to control glucose had not advanced to the point where those subjects were diagnosed with NIDDM. Thus, the

specification, as originally filed, discloses all of the elements of the currently pending claims.

Applicants request reconsideration and withdraw of the 35 U.S.C. § 112, first paragraph rejection of claims 10-38, 41, and 44-54 for new matter.

## III. Rejection under 35 U.S.C. § 112, First Paragraph, Written Description

Claims 44-58 stand rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed for at least the reasons which follow.

In support of this rejection, the Examiner alleges that:

> There is no description in the instant specification for the claimed method of treating an individual with impaired tolerance who has [not] been diagnosed with non-insulin dependent diabetes mellitus (NIDDM) by administering a **composition comprising an exendin or a variant of said exendin, wherein the exendin is exendin-3 or exendin-4** as claimed.

*Office Action*, at page 5 (emphasis in original). The Examiner also alleges that "there is no support for a method of reducing a risk of a cardiovascular or cerebrovascular events by administering to an individual a **composition comprising an exendin or a variant thereof** in the manner claimed in claims 55-58." *Id.* at page 6 (emphasis in original). Applicants respectfully disagree.

The present specification, including the incorporated commonly owned applications, clearly demonstrates that Applicants were in possession of the claimed genus of exendins as currently claimed at the time the application was filed. The specification discloses methods of treating IGT and reducing a risk of cardiovascular and cerebrovascular events by administering a composition comprising a compound which binds to a receptor for GLP-1. In addition, the specification discloses exendins and exendin variants which bind to a receptor for GLP-1. *See, e.g.*, specification at page 6, line 22 through page 7, line 2 and page 10, line 3 through page 11, line 11. Applicants

have provided sufficient guidance and working examples as to structural and functional characterization of the claimed exendin peptides, *e.g.*, through extensive disclosure of exendin and exendin analog sequences and assays for verifying activity in methods for treating individuals with IGT and for reducing the risk of cardiovascular and cerebrovascular events.

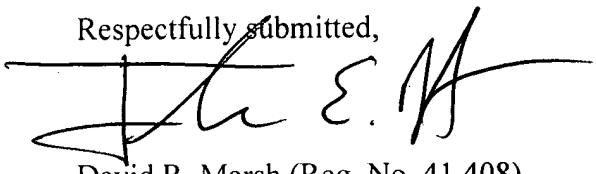
While Applicants maintain that the specification, including the references incorporated by reference, sufficiently describe exendins and variants thereof, to expedite prosecution, the claims have been amended without prejudice to or disclaimer of the underlying subject matter to refer to exenind-3 and exendin-4, which the Examiner has admitted are described in the specification. *See, e.g., Office Action*, at page 6. It is submitted, therefore, that the present claims meet the written description requirement, and withdrawal of this rejection is respectfully requested.

Accordingly, for at least the foregoing reasons, the rejection of claims 44-58 under 35 U.S.C. § 112, first paragraph is traversed. Reconsideration and withdrawal of this rejection are respectfully requested.

## Conclusion

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5085 should any additional information be necessary for allowance.

Respectfully submitted,



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